

FDA PUBLIC MEETING ON CBD
5-31-19

My name is Rod Kight. I am an attorney who represents cannabis businesses. Thank you for allowing me this opportunity to speak.

Numerous studies have found that CBD is safe. According to the World Health Organization, it is non-toxic, non-addictive, and non-intoxicating.

People who use CBD deserve helpful guidance and reasonable regulations that will allow them to produce, sell, and safely use CBD products.

The FDA's approval of a CBD seizure drug last year has created a complex legal scenario under Section 301(ll) of the Food, Drug & Cosmetic Act. Fortunately, there are at least two paths forward:

The first path is hemp extract.

Section 301(ll) prohibits a drug from being added to food only if the substance:

is intended to diagnose, cure, mitigate, treat, or prevent disease through its use in the food, as shown objectively by marketing and labeling representations; and

is the exact same moiety as the active ingredient in an approved drug and is added to the food in the same dosage range as authorized by the new drug approval.

Hemp extract as a food is an exception to section 301(ll) notwithstanding that it contains CBD. This is because CBD is a naturally occurring constituent inherent in hemp, which has been marketed and used at least since the Civil War. The prohibition on marketing a drug in food applies only to a substance that is added to food and does not apply to a substance that is in food, even where the substance is identical to an approved drug. Additionally, hemp extract contains dozens of compounds and is not the same moiety as the FDA approved CBD drug.

The second path is for CBD itself.

The mere chemical identity with an approved drug not render a substance a "drug" in the absence of marketing claims.

Section 301(ll) excepts from its prohibition a drug that was "marketed in food before any approval of the drug" or before substantial clinical investigations involving the drug were instituted. "Marketed in food" simply means that the substance has been "in food" that has been marketed, regardless of whether or not it has been separately promoted. Once a substance has been marketed in food as an inherent natural constituent of a food (as with CBD), it remains within the "marketed in food"

exemption even if that constituent is later isolated and then added to other food, as is the case with numerous CBD products currently on the market.

Thank you.